

Serial Number: 09/753,139

Filing Date: December 29, 2000

Title: DESIGN AND USE OF ADVANCED ZINC CHELATING PEPTIDES TO REGULATE MATRIX METALLOPROTEINASES

REMARKS

Applicants have carefully reviewed and considered the Office Action mailed on August 5, 2004.

Applicants have amended the specification at page 8 to correct an inadvertent typographical error. Claims 6 and 22 were amended to delete SEQ ID No. 11. Support for the changes to claims 6 and 22 appears in the specification, beginning at page 19. Claim 22 was amended to depend from claim 20, and thus to be consistent with the format of claim 6.

Applicants submit that these changes do not constitute new matter.

Restriction/Election Requirement

The Examiner's indication, at page 10 of the Office Action, of enablement for more than the elected species is a clear indication that she has examined more than the elected species. However, the Examiner's withdrawal of claims 4-6, 20, and 21 for being directed to non-elected species is inconsistent with an extension of examination beyond the elected species.

Clarification of the scope of examination is requested. Applicants note that claims 22 and 23 were not included in the groupings in the requirement for restriction mailed June 30, 2004, but claims 22 and 23 were examined. As amended, the claims should be examined with elected Group I. Applicants note further that the examination of claim 22 is inconsistent with the withdrawal from consideration of claim 6. The claims are of the same scope, and differ only as compound and composition.

Applicants request reconsideration of the Examiner's statement, "[a]s to the Markush groups recited by claims 2, 6, 18 and 22 they cover thousands of chemical compounds of different chemical structure, i.e. they are not in the proper form." Office Action at page 4. Claims 2, 6, 18, and 22 meet all the prerequisites of proper Markush claims. They are in the proper written format, and the members of the Markush group belong to a recognized chemical class, compounds that bind zinc. MPEP § 2173.05(h). The mere size of the Markush group is not a factor in determining the propriety thereof. Furthermore, Markush groups by their very nature include different chemical structures. It is the community of properties possessed by the members of the Markush group that make such a group proper, not the structure of the members

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or the size of the group. *Ibid.* Applicant requests clarification and reconsideration of the restriction requirement.

Objections to Specification

The Examiner has objected to the specification for use of the term *chelator*. In the Examiner's view, “[t]he scope of the invention covers chemical compounds that are not chelators, but nonetheless bind zinc; see page 13, line 3.” Office Action at page 5. This objection is respectfully traversed.

It is axiomatic that an applicant is entitled to be his own lexicographer. An inventor may set forth an uncommon definition of a term in the specification so long as the definition is presented with reasonable clarity, deliberateness, and precision, and so that one of ordinary skill in the art is given notice of the uncommon definition. MPEP § 2111.01, section III. Applicants' definition meets all of these criteria, and it is clear from the Examiner's own words that the definition is clear to her. Withdrawal of this objection is respectfully requested.

In response to the Examiner's request to delete the letter *n* at page 8, line 12 of the specification, applicants have corrected the spelling of the intended word *in* in lieu of deletion. Withdrawal of this objection is respectfully requested.

Objections to Claims

The Examiner has requested that all claimed abbreviations recited for the first time be expanded. This objection is respectfully traversed.

It is axiomatic that claims are not read in a vacuum. One must read and analyze the claims in light of the specification, the teachings of the prior art, and the claim interpretation given the claim by one of ordinary skill in the pertinent art at the time the invention was made. MPEP § 2173.02.

The abbreviated claim terms are either described in detail in the specification or are so well known in the art as not to require description, e.g., EDTA. Withdrawal of this objection is respectfully requested.

The Examiner has objected to the claims for the use of the term *chelator*. This objection

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is similar to that made to the specification, *supra*. This objection is respectfully traversed for the reasons set forth above and for the following additional reasons. An applicant may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See MPEP § 2111.01 and *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Applicants have set forth very clearly in the specification their definition of zinc chelator. The definition is clear to the Examiner, as paraphrased by her in the Office Action at page 5. In addition the Examiner is reminded that “[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.” MPEP § 2173.02. Withdrawal of this objection is respectfully requested.

Claims 2, 6, 18, and 22 have been objected to for reciting an improper Markush group: “[a]lthough the recited chemical compounds share the same function of inhibiting metaloproteases [sic], their structure is versatile.” Office Action at page 6.

As Applicants have pointed out *supra*, claims 2, 6, 18, and 22 meet all the prerequisites of proper Markush claims. They are in the proper written format, and the members of the Markush group belong to a recognized chemical class, compounds that bind zinc. MPEP § 2173.05(h). Markush groups by their very nature include different chemical structures. It is the community of properties possessed by the members of the Markush group that makes a Markush group proper, not the structure of the members or the size of the group. *Ibid.* The Examiner has admitted that the members share the same function. Therefore, by the Examiner’s own admission and according to the requirements set forth in MPEP § 2173.05(h), claims 2, 6, 18, and 22 are proper Markush claims. Withdrawal of this objection is respectfully requested.

Claim 22 was objected to as being dependent upon claim 21, which is directed to non-elected species. Pending clarification of the scope of examination conducted (see above under Restriction/Election requirement), the Examiner is requested to hold this objection in abeyance.

Claim 22 was further objected to under 37 C.F.R. § 1.75(c), as “being of improper dependent form for failing to further limit the subject matter of a previous claim.” Office Action at page 6. Applicants have amended claim 22 to depend from claim 20 and thus to be consistent

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with the format of product claim 6. Withdrawal of this objection is respectfully requested.

Rejection of Claims Under 35 U.S.C. § 112, 2nd Paragraph

Claims 1-3, 7, and 15-23 were rejected under 35 U.S.C. § 112, 2nd paragraph. Applicants note that claims 20 and 21 were withdrawn from consideration by the Examiner at page 5 of the Office Action and apparently do not belong in this rejection. Clarification is requested.

The Examiner stated that the term *MMP regulator* is confusing, “because Applicants’ invention is directed to MMP inhibitors.” Office Action at page 7. This rejection is respectfully traversed. As Applicants have noted *supra* (under Claim Objections), it is axiomatic that claims are not read in a vacuum. One must read and analyze the claims in light of the specification, the teachings of the prior art, and the claim interpretation given the claim by one of ordinary skill in the pertinent art at the time the invention was made. MPEP § 2173.02.

When read in light of the specification, there should be no confusion regarding what Applicants intend by the term *MMP regulator*. Applicants direct the Examiner’s attention to Page 4, first full paragraph of the specification, where Applicants disclose regulation as tantamount to control of MMP activity. Applicants further disclose inhibition of the enzymatic activity of the MMP at page 12, penultimate line. The Examiner is again reminded that “[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.” MPEP § 2173.02.

Applicants submit that indefiniteness depends on whether one of skill in the art would understand the scope of the claim when the claim is read in light of the specification. *North American Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Miles Laboratories Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993). Withdrawal of this rejection is respectfully requested. Examiner rejected claim 22 as confusing by virtue of the inclusion therein of SEQ ID NO: 11. Applicants have amended claims 6 and 22 to delete SEQ ID NO: 11. Withdrawal of this rejection is respectfully requested.

Rejection of Claims Under 35 U.S.C. § 112, 1st Paragraph**1. Written Description Requirement**

Claims 1-3, 7, and 15-23 were rejected under 35 U.S.C. § 112, 1st paragraph. Applicants note that claims 20 and 21 were withdrawn from consideration by the Examiner at page 5 of the Office Action and apparently do not belong in this rejection.

The Examiner stated that “[t]he claims are missing the description of the matrix protease to be inhibited by the claimed inhibitors because the genus of matrix proteases is a large genus and it is unlikely that all matrix metalloprotease [sic] share their inhibitors, [sic - .]” Office Action, sentence bridging pages 7 and 8. This rejection is respectfully traversed.

Applicants’ invention is directed to regulators of MMPs, not to the MMPs themselves. Applicants have described at page 2 of the specification the relatively small number of members of the MMP family that have been isolated and characterized, as well as other potential members of the family. One would understand that Applicants intend their invention to regulate those known MMPs and those yet to be isolated and characterized. If the Examiner is of the opinion that all MMPs will not be inhibited by Applicants’ claimed regulators, Applicants’ submit that a written description requirement rejection is not the appropriate rejection to be made.

Withdrawal of this aspect of the rejection is respectfully requested.

The Examiner rejected claims 1 and 15 because the structure of the claimed MMP regulators is allegedly not described sufficiently in the claims and specification. Office Action at page 8. In addition, the Examiner stated that “[p]roviding several members of zinc chelating (or rather zinc binding) compounds … does not allow for identifying the whole genus of zinc chelators comprising chemicals of versatile structures. Thus, a zinc-binding compound used for construction of inhibitor [sic] should be identified by its structure.” *Ibid.* The Examiner stated further that “[n]owhere in the specification Applicants state which residues of TIMP are considered to form TIMP derived polypeptide.” *Ibid.* The Examiner stated further that “Applicants themselves define SEQ ID NO:1-3, which they use for constructing inhibitors, as definite fragments of MMP not any TIMP (see page 14, line 21 and further, and Table 1). However, they even do not disclose the amino acid sequence of said MMP.” Office Action at page 9 (emphasis in original). Finally, the Examiner summarizes her position, “the genus of

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claimed MMP inhibitors comprises thousands of chemical compounds whereas Applicants teach only a few such compounds Providing one skilled in the art with these representatives of the claimed genus is not sufficient to [sic] for identifying structural characteristics of the whole genus." *Ibid.* This rejection is respectfully traversed.

MMPs contain a zinc molecule located in the active site. If the zinc is blocked or removed, enzymatic activity of the MMP can be inhibited. Applicants have found, using visualization programs, that the TIMP molecules make significant contact with the area surrounding the MMP active site in the vicinity of the MMP-bound catalytic zinc. Specification at page 7. This was accomplished by molecular modeling with known TIMPs and known MMPs. See specification at page 28. Applicants need not provide structures of known compounds.

In one embodiment of Applicants' invention, SEQ ID NOs: 1-3 are derived from three separate regions of TIMPs I-IV that contact MMPs. TIMPs I-IV are specific known proteins with known structure. The MMP amino acids disclosed in the specification are those of the known, isolated, and characterized MMPs. Applicants have identified the variant and conserved amino acids in the MMP-TIMP contact interfaces. Specification at page 29. These three regions of TIMPs I-IV are in close proximity to the MMP catalytic zinc site at amino acids 2-9, 62-73, and 97-105 of the MMP, i.e., the three TIMP-derived sequences *span* or contact the MMP at those amino acids of the MMPs. Thus, SEQ ID NOs: 1-3 are fragments of TIMPs I-IV and not fragments of MMPs. Applicants have indeed stated those residues of TIMPs considered to form TIMP-derived polypeptides. See below for a discussion of additional TIMP-derived polypeptides.

The Court of Appeals for the Federal Circuit (CAFC) has recently (October 7, 2004) decided a case that is relevant to the present issue of whether the specifically disclosed zinc chelators and MMP regulators are sufficient to describe the entire genera. *Bilstad v. Wakalopulos*, 03-1528. Page numbers of this case used in the following discussion are those obtained after printing the case from the CAFC website. A copy is attached for the Examiner's convenience.

The court stated that "disclosure of a single species within a genus may be enough

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support for a claim directed to the genus.” *Bilstad* at 13, citing *In re Rasmussen*, 650 F.2d 1212, 1215 (CCPA 1981). In addition, the court emphasized that there must be a discussion of what persons skilled in the art would have understood from the disclosure, and there must be findings on the degree of predictability or unpredictability of technical variations in the particular art. *Bilstad* at 17. Because the Board failed to consider the knowledge of one skilled in the art and the level of predictability in the field, the case was remanded so that the Board could apply the proper test for descriptive support.

Applicants are not aware of any unpredictability in the art with respect to zinc chelators. One would understand from the disclosure that any zinc chelator would function in Applicants’ invention. Furthermore, the specification provides the requisite disclosure to indicate that Applicants were in possession of the entire genus of TIMP-derived peptides. Once the structure of the MMP is known, the exact sequence of the TIMP-derived peptide can be discerned from a visualization program. One would choose the part of a known TIMP that made the closest approach to the known MMP in the vicinity of the catalytic zinc. Specification at page 8. The binding specificity of the peptide will bring the zinc chelator into molecular proximity of the MMP-bound zinc in such a way to allow ligation. Specification at pages 7-8. The procedure is predictable, and one would understand from the disclosure that variations from the preferred embodiments would also be predictable, so as to place the entire genus in Applicants’ possession at the time of filing. Withdrawal of this aspect of the rejection is respectfully requested.

2. Scope of Enablement

Claims 1-3, 7, and 15-23 were rejected under 35 U.S.C. § 112, 1st paragraph. Applicants note that claims 20 and 21 were withdrawn from consideration by the Examiner at page 5 of the Office Action and apparently do not belong in this rejection. The Examiner stated that the specification does not provide enablement for more than ChePep-1, ChePep-2, ChePep-3, ChePep-4, ChePep-5, ChePep-6, and PSDE covalently linked to SEQ ID NO:2. Office Action at page 10. This rejection is respectfully traversed.

The Examiner stated that “[t]he claims are broader than the enablement provided by the disclosure with regard to the *extremely large number of inhibitors of MMP* [sic] covered by

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subgenera (1) – (3).” Office Action at page 10 (emphasis added). The three subgenera in question are:

- 1) any inhibitor of any MMP that consists of a zinc chelator and a TIMP-derived peptide;
- 2) any inhibitor of any MMP that consists of AFTA and a TIMP-derived peptide; and
- 3) any inhibitor of any MMP that consists of a zinc chelator and a peptide derived from a TIMP that contains at least one cysteine residue. *Ibid.*

As Applicants have pointed out above, in connection with the written description requirement rejection, Applicants intend their invention to regulate those known MMPs and those yet to be isolated and characterized with MMP regulators comprising TIMP-derived peptides from TIMPs known at or before filing and subsequent thereto. Only a relatively small number of members of the MMP family have been isolated and characterized. Only a small number of TIMPs are known. TIMPs I-IV are specific known proteins with known structure. Therefore, contrary to the Examiner’s assertion, the number of MMP regulators is not extremely large.

In addition, Applicants are not aware of any unpredictability in the art with respect to zinc chelators. One would understand from the disclosure that any zinc chelator would function in Applicants’ invention. If the Examiner disagrees, she has the burden of producing documentation showing otherwise.

Furthermore, Applicants’ specification is replete with guidance on how to practice their invention. Once the structure of the MMP is known, the exact sequence of the TIMP-derived peptide can be discerned from a visualization program. One would choose as the derived peptide the part of a known TIMP that made the closest approach to the known MMP in the vicinity of the catalytic zinc. Specification at page 8. The binding specificity of the peptide will bring the zinc chelator into molecular proximity of the MMP-bound zinc in such a way to allow ligation. Specification at pages 7-8. The procedure is so well-detailed in the specification that undue experimentation would not be required. If the Examiner disagrees that using the visualization program procedure would lead to operative embodiments without undue experimentation, she has the burden of producing documentation showing otherwise. The Examiner has not commented at all on this procedure. The program precludes the need for large amounts of

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

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synthesis and screening that the Examiner apparently views as necessary to practice Applicants' invention. Office Action at page 11. Withdrawal of this aspect of the rejection is respectfully requested.

Conclusion

Applicant respectfully submits that all claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (516) 795-6820 to facilitate prosecution of this application.

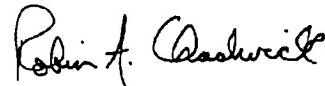
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

STEPHEN QUIRK ET AL.,

By their Representatives,

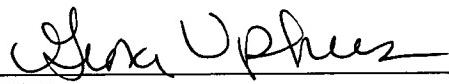
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Date November 5, 2004 By _____
Robin A. Chadwick
Reg. No. 36,477

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 5 day of November, 2004.

Name Gina M. Uphus

Signature 

United States Court of Appeals for the Federal Circuit



03-1528
(Interference No. 104,832)

ARNOLD C. BILSTAD, BRADLEY H. BUCHANAN,
ALAN W. MARTILLA, and ARCHIE WOODWORTH,

Appellants,

v.

GEORGE WAKALOPULOS and EDUARDO R. URGILES,

Appellees.

Keith V. Rockey, Wallenstein, Wagner & Rockey, Ltd., of Chicago, Illinois, argued for appellants. With him on the brief were Daniel N. Christus and Robert W. Diehl. Of counsel on the brief were Mark J. Buonaiuto, Assistant General Counsel; and Francis C.M. Kowalik, Corporate Counsel, Law Department, Baxter International Inc., of Deerfield, Illinois.

Douglas E. Olson, Paul Hastings Janofsky & Walker, LLP, of San Diego, California, argued for appellees. With him on the brief were Howard S. Wisnia, John E. Peterson, and Elizabeth L. Brann.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

03-1528

ARNOLD C. BILSTAD, BRADLEY H. BUCHANAN, ALAN W. MARTILLA
and ARCHIE WOODWORTH

Appellants,

v.

GEORGE WAKALOPULOS and EDUARDO R. URGILES,

Appellees.

DECIDED: October 7, 2004

Before BRYSON, Circuit Judge, PLAGER, Senior Circuit Judge, and LINN, Circuit Judge.

LINN, Circuit Judge.

Arnold C. Bilstad, Bradley H. Buchanan, Alan W. Martilla, and Archie Woodworth (collectively “Bilstad”) appeal from: (1) a March 31, 2003 decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (“Board”) and (2) a May 23, 2003 decision of the Board on reconsideration awarding judgment in Interference No. 104,832 to George Wakalopoulos and Eduardo R. Urgiles (collectively “Wakalopoulos”). Bilstad v. Wakalopoulos, Inter. No. 104,832, Paper 69 (Bd. Pat. App. & Inter. May 23, 2003) (“Reconsideration Decision”); Bilstad v. Wakalopoulos, Inter. No. 104,832, Paper 62 (Bd. Pat. App. & Inter. Mar. 31, 2003) (“Original Decision”). Because the Board’s claim construction was correct, and because the Board did not abuse its discretion in dismissing Bilstad’s motion for leave to belatedly add additional claims to

the count, we affirm those portions of the Board's decision. However, because the Board failed to apply the correct standard in deciding whether Bilstad's disclosure supported the count, we vacate that portion of the Board's decision and remand.

I. BACKGROUND

This interference was declared on March 30, 2002 between an application of Bilstad, Application Serial No. 09/294,964, filed April 20, 1999, and a patent of Wakalopoulos, U.S. Patent No. 6,140,657 ("the '657 patent"), filed March 17, 1999 and issued October 31, 2000. The claimed subject matter relates to an apparatus for sterilizing three-dimensional objects using ionizing radiation without affecting the target objects in a deleterious manner.

Bilstad provoked the interference by copying claims 1, 5-8, 11, and 16-17 of the '657 patent into Bilstad's pending application as claims 57-64, as well as adding a paraphrased version of Wakalopoulos's claim 18 as claim 65. The Board declared the interference, designating claim 1 of the '657 patent as the only count and identifying Bilstad claims 57-65 as corresponding to the count. The count reads as follows, with the disputed portion underlined:

A sterilization apparatus comprising,

an electron beam tube having a window permitting emergence of an electron beam from said tube into an ambient gaseous environment while preserving a vacuum environment in the tube, the electron beam having a trajectory within a plasma cloud defining a reactive volume stimulated by interaction of the electron beam with the ambient environment, with a beam energy less than 100 kV at the target, and

a moveable member manipulating objects in a plurality of directions within the reactive volume wherein the manipulated objects are sterilized.

In the "Notice Declaring Interference" issued by the Patent and Trademark Office, the Board included a standing order that required, among other things, "a conference call to the administrative patent judge" before the filing of any contested miscellaneous

motion. Subsequently, the Administrative Patent Judge designated to handle the interference entered an order setting deadlines for the filing of preliminary motions as prescribed by 37 C.F.R. § 1.636(a). The order established a “preliminary motion period” for filing motions under 37 C.F.R. § 1.633 (“Rule 633”), paragraphs (a) through (h), and a “Rule 633(i) period” for filing motions under paragraphs (i) and (j) of Rule 633.

During the preliminary motion period, Wakalopulos filed Preliminary Motion 1 under Rule 633(a), which allows a movant to seek judgment based on an assertion that an opponent’s claim, designated to an interference count, is not patentable to that opponent. 37 C.F.R. § 1.633(a) (2003). Wakalopulos asserted, in its preliminary motion, that the involved claims of the Bilstad patent lacked adequate written description support under 35 U.S.C. § 112, ¶1 for the claim limitation “a moveable member manipulating objects in a plurality of directions within the reactive volume.” In addition to its opposition to Wakalopulos’s motion for judgment, Bilstad sought an extension of the Rule 633(i) period. Under Rule 633(i), an opponent to a motion filed under Rule 633(a) is permitted to file a preliminary motion under Rule 633(c) to add or amend claims to address the alleged unpatentability of the claims. 37 C.F.R. § 1.633(i) (2003). The Board denied Bilstad’s request for an extension of time, and Bilstad did not file a timely motion under Rule 633(i).

On September 27, 2002, the Board conducted a hearing on Wakalopulos’s preliminary motion and, on March 31, 2003, granted judgment in favor of Wakalopulos. Original Decision, slip op. at 28. In that judgment, the Board concluded that all of Bilstad’s involved claims were unpatentable under 35 U.S.C. § 112 for lack of written description. In reaching this conclusion, the Board focused on the term “plurality,” which

it construed to “connote[] an indefinite numerical range. The range is bounded by two at the lower end and unbounded or infinite at the upper end.” *Id.* at 24. The Board also stated that “‘plurality’ is a generic word which encompasses within its meaning any number at least two or greater.” *Id.* Based on Bilstad’s written description, however, the Board concluded that Bilstad described manipulating objects “in a small number of directions,” and that “Bilstad’s original specification does not provide a written description of manipulations in a large number of directions.” *Id.* The Board thus found the written description lacking and granted judgment in Wakalopulos’s favor.

Bilstad sought reconsideration of the Board’s decision, arguing that: (1) the Board erred in construing “plurality” as a range; (2) Bilstad was prejudiced because the Board adopted a definition of “plurality” that neither party proffered; and (3) given the Board’s finding that Bilstad discloses a member capable of manipulating objects in a small number of directions, “the mere disclosure of movement in two or three directions would be adequate . . . support” for “plurality” under § 112, ¶1. At the same time, Bilstad filed a miscellaneous motion under 37 C.F.R. § 1.635¹ seeking leave to belatedly add to the Bilstad application claims designated as corresponding to the count. The motion essentially sought leave to file a Rule 633(i) motion after the deadline for filing such motions had passed. Along with the Rule 635 motion, Bilstad filed Motion 5 which sought to add to the count a number of claims not including the term “plurality.”

¹ 37 C.F.R. § 1.635 recites that “[a] party seeking entry of an order relating to any matter other than a matter which may be raised under § 1.633 . . . may file a motion requesting entry of the order.” 37 C.F.R. § 1.635 (2004).

In its reconsideration decision of May 23, 2003, the Board addressed both Bilstad's reconsideration motion and the miscellaneous motion under 37 C.F.R. § 1.635. The Board was unpersuaded by Bilstad's arguments regarding the construction of "plurality" and the extent of support for the term in Bilstad's written description. See generally Reconsideration Decision, slip op. at 7-14. As to Bilstad's Rule 635 motion, the Board noted that Bilstad failed to follow the procedure in the standing order requiring a conference call prior to the filing of such motions. As such, the Board dismissed Bilstad's miscellaneous motion and returned as unauthorized the accompanying motion to add claims. Id. at 4 n.1. Because the Board noted that "the matters raised in the miscellaneous motion appear also to have been raised as part of Bilstad's request for reconsideration," the Board addressed, to that extent, the merits of Bilstad's motion. Id. The Board concluded that "Bilstad's current position is the result of choices made by Bilstad" and that "Bilstad was not denied the opportunity to file a motion to amend or add claims or to change the count," but rather "Bilstad did not take advantage of the opportunity afforded." Id. at 7.

Bilstad timely appealed the Board's Original Decision and Reconsideration Decision to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II. DISCUSSION

A. Standard of Review

Before the Board, the burden of establishing by a preponderance of the evidence that Bilstad's application lacked sufficient disclosure under 35 U.S.C. § 112, ¶ 1 fell on Wakalopoulos as movant. Kubota v. Shibuya, 999 F.2d 517, 519 n.2, 522 (Fed. Cir. 1993). As we explained in Kubota, under the old interference rules, "a party copying

claims for the purpose of provoking an interference bore the burden of proving by clear and convincing evidence that it had the ‘right to make’ the claim.” Id. at 521. However, with respect to the new interference rules—at issue in this case—we said:

It seems to us that, while the burden initially may be on a party seeking to provoke an interference, or seeking to obtain entitlement to a priority date, once an interference has been declared and a party seeks to change the status of the parties by motion, the burden is then on the movant under the new rules, rather than on the party originally provoking the interference or obtaining entitlement.

Id. at 522. The logic behind this rule is based, in part, on 37 C.F.R. § 1.655(a), which states, “The burden of showing that an interlocutory order should be modified shall be on the party attacking the order.” The declaration of interference is an interlocutory order that is presumed to be correct. See Kubota, 999 F.2d at 520-21 (adopting the Commissioner’s interpretation that a declaration of interference is an interlocutory order presumed to be correct under 37 C.F.R. § 1.655(a)). Thus, once Bilstad convinced the examiner that he was entitled to an interference, that decision was presumed to be correct, and Wakalopulos bore the burden of proving that it was incorrect by a preponderance of the evidence.

Interpretation of an interference count is a question of law, reviewed de novo. Credle v. Bond, 25 F.3d 1566, 1571 (Fed. Cir. 1994). Whether an application complies with the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact, reviewed for substantial evidence. Singh v. Brake, 317 F.3d 1334, 1343 (Fed. Cir. 2003); see also In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (adopting the substantial evidence standard of the Administrative Procedure Act in reviewing factual findings of the Board). Substantial evidence is merely “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” In re Zurko, 258

F.3d 1379, 1384 (Fed. Cir. 2001) (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938)).

The Board's decision, denying leave for Bilstad to file a belated motion under 37 C.F.R. § 1.633(i), is reviewed for an abuse of discretion. Rapoport v. Dement, 254 F.3d 1053, 1058 (Fed. Cir. 2001). An abuse of discretion is found if the decision: "(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." Id.; Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51 (Fed. Cir. 1994).

B. Section 112 Analysis

Bilstad argues that the Board committed two errors in concluding that Bilstad's application provided insufficient written description to support the count, namely: (1) the Board erroneously construed the term "plurality" as used in the count, and (2) the Board erred in insisting that Bilstad's application must describe every embodiment within the range construction given by the Board to the term "plurality." We consider each of these arguments in turn.

1. Count Construction

Bilstad first argues that the Board's decision must be reversed because its claim construction of the term "plurality" is erroneous. In particular, Bilstad argues that the Board's combination of multiple dictionary definitions to arrive at a range is inconsistent

with precedent.² Wakalopulos argues instead that the Board properly construed “plurality” because the written description of the ’657 patent does support a broad construction and the Board’s analysis is fully consistent with precedent.

Before the Board, Bilstad and Wakalopulos offered competing definitions of the term “plurality.” Wakalopulos argued that “plurality” means “a large number; multitude,” whereas Bilstad argued that “plurality” simply means “two or more items.” The Board began by noting that the parties did not argue that “plurality” had any special meaning in the art, nor did the parties argue that Bilstad’s specification provided a definition of “plurality.” Original Decision, slip op. at 23. The Board then consulted a dictionary to ascertain the ordinary meaning of “plurality” and was confronted with multiple definitions, including those proffered by the parties. Id. at 24. Specifically, the Board noted that Webster’s Third New International Dictionary included multiple definitions of “plurality,” including “the state of being plural,” “the state of being numerous,” and “a large number or quantity: MULTITUDE.” Id. at 24 (quoting Webster’s Third New International Dictionary 1745 (Philip Babcock Gove, Ph. D. ed. 1993) (“Webster’s”)). The Board also included the definition of “plural” from the same dictionary: “relating to or consisting of or containing more than one.” The Board went on to state:

As is apparent from the Webster’s definitions, the ordinary meaning of plurality encompasses both parties’ proposed meanings. Therefore, we do not accept either party’s proposed definitions because they are incomplete. Two may properly be referred to as a plurality and so may a

² Bilstad also argues that the Board erred in construing the term “plurality” in view of Bilstad’s disclosure, instead of looking to the ’657 patent. Bilstad cites In re Spina, 975 F.2d 854 (Fed. Cir. 1992), for the proposition that a count is construed in view of the originating disclosure. Wakalopulos concedes that the Board erred in this respect. Because we conclude that the construction of the term “plurality” is the same in view of either disclosure, we need not reach this issue.

large number. Thus, “plurality” connotes an indefinite numerical range. The range is bounded by two . . . and . . . infinit[y]

Original Decision, slip op. at 24.

We see no error in the Board’s construction of “plurality.” When confronted with competing arguments, the Board looked to a dictionary to ascertain the ordinary meaning of “plurality.” Here, the dictionary shows ordinary meanings of “plurality,” including: “relating to or consisting of or containing more than one,” “the state of being numerous,” and “a large number or quantity.” Webster’s, at 1745. The Board then looked to the written description for context in ascertaining the meaning of “plurality,” determined that the dictionary definitions and both Bilstad’s and Wakalopoulos’s proffered definitions were consistent with Bilstad’s disclosure, and construed the term to encompass all of those meanings. As we have stated, “[i]f more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings.” Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300 (Fed. Cir. 2003) (citing Tex. Digital Sys. Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2002)). “[W]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning.” Renishaw PLC v. Marposs Societa’ Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998); see also Tex. Digital, 308 F.3d at 1203. None of these definitions is inconsistent with the Bilstad disclosure or the Wakalopoulos disclosure.

With respect to the Bilstad disclosure, the Board found that Bilstad disclosed manipulation in a small number of directions. Thus, the Bilstad disclosure is entirely consistent with the meaning of “plurality” as “relating to or consisting of or containing

more than one." With respect to "the state of being numerous" and "a large number or quantity," we see nothing in Bilstad's disclosure that disclaims, disavows, or is inconsistent with such definitions of plurality. See Brookhill-Wilk, 334 F.3d at 1300. Because all of the definitions are consistent with the Bilstad disclosure, the term "plurality" when construed in view of the Bilstad disclosure is entitled to the full extent of its ordinary meaning.

Similarly, each of the ordinary meanings of "plurality" is consistent with the disclosure of the '657 patent. First, nothing in the written description of the '657 patent defines the term "plurality," nor is there any disclaimer or disavowal of the ordinary meaning of the term "plurality." See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). Second, although, as Bilstad argues, Wakalopulos uses the term "plurality" to describe a set of three items, this is simply one use of the term in a particular context. This single use alone does not limit the term. Third, the Wakalopulos written description, in Figure 3 and its accompanying text, illustrates an embodiment wherein a glove box arm is provided to allow a user to place his hand in and pick up and manipulate an object to be sterilized. This description is consistent with a construction of "plurality" that includes everything from "relating to more than one" to "a large number or quantity." Thus, the Wakalopulos written description does not limit the ordinary meaning of "plurality." We therefore conclude that "plurality" encompasses all of the relevant definitions; namely, relating to or consisting of or containing more than one, the state of being numerous, and a large number or quantity.

Bilstad, however, argues that the Board improperly incorporated the several dictionary definitions into a range from two to infinity. While it is common to consider

the full meaning of “plurality” as any number greater than one, the Board’s definition does little more than incorporate the several distinct definitions into a single one covering the entire scope of “plurality.” In combining the definitions into a single one, the Board did not change the scope of the term or alter the ordinary meanings in any significant way. Thus, we affirm the Board’s construction of the term “plurality.”

Bilstad’s other arguments regarding alleged claim construction errors made by the Board have been considered and are not deemed persuasive.

2. Written Description

Bilstad next argues that the Board erred in insisting that Bilstad’s application must describe every embodiment within the range of two to infinity to support the count, copied by Bilstad, under the Board’s construction of the term “plurality.”

The question requires consideration of whether the Bilstad disclosure, as filed, “reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date.” Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995).

With particular relevance to this case, several cases have considered the issue of written description support for an added genus claim when only a species is disclosed. In In re Smythe, our predecessor court said, “We cannot agree with the broad proposition . . . that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in section 112.” 480 F.2d 1376, 1382 (CCPA 1973). Smythe involved the question of whether a disclosure of air as a segmentizing medium was

sufficient written description to support the broader claim language “inert fluid,” though the term “fluid” did not appear in the written description. The court concluded,

We believe that the use of an inert fluid broadly in this invention would naturally occur to one skilled in the art reading the description of the use of air or other gas as a segmentizing medium to separate the liquid samples. While fluid is a broader term, encompassing liquids, as noted by the solicitor, the specification clearly conveys to one skilled in the art that in this invention the characteristics of a fluid are what make the segmentizing medium work in this invention.

This is not a case where there is any unpredictability such that appellants’ description of air or other inert gas would not convey to one skilled in the art knowledge that appellants invented an analysis system with a fluid segmentizing medium.

Id. at 1383. Similarly, in In re Rasmussen, 650 F.2d 1212, 1215 (CCPA 1981), our predecessor court considered whether a written description disclosing a single method of applying adhesive supported the amended claim containing the broad language “adheringly applying.” The court explained: “[T]hat a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment.” Id. The court stated that “one skilled in the art who read Rasmussen’s specification would understand that it is unimportant how the layers are adhered, so long as they are adhered.” Id. Thus, our predecessor court recognized that disclosure of a single species within a genus may be enough support for a claim directed to the genus.

In Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575-77 (Fed. Cir. 1985), this court affirmed a trial court’s finding that several open-ended ranges were supported by a parent written description. In particular, this court affirmed the trial court’s conclusion that the limitation “protein content of at least about that of solvent extracted soybean meal” was supported by the written description disclosing solvent extracted soybean meal with a protein content of about 50%. Id. at 1575-76. Although open-ended and although the parent disclosure did not teach materials having greater

than 50% protein content, this court said, "The trial court found that the parent disclosure does support the claim language, based on the 1964 disclosure and on consideration of the knowledge possessed by those skilled in the art of extrusion of both farinaceous and proteinaceous vegetable materials in 1964." Id. at 1576. We then noted that soybean meals with protein contents above 50% were readily available commodities in 1964. We concluded that "the court did not clearly err in determining that the parent's disclosure adequately supports the protein content of the claims in issue." Id. at 1576.

Thus, this court has continued to apply the rule that disclosure of a species may be sufficient written description support for a later claimed genus including that species. As we explained in Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.:

Claim 1 was properly rejected because it recited an element not supported by Fox's disclosure, i.e., a lockout "on the stapler." It does not follow, however, that Fox's disclosure could not support claims sufficiently broad to read on a lockout off of the cartridge. If Fox did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly (within the limits imposed by the prior art) to exclude the lockout's exact location as a limitation of the claimed invention. Such a claim would not be unsupported by the specification even though it would be literally infringed by undisclosed embodiments.

93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996) (citations omitted); see also Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1377-78 (Fed. Cir. 2000) (affirming the district court's finding that disclosure of only identical half-shells was sufficient written description support for a claim encompassing both identical and non-identical half-shells).

There are, however, exceptions to the general rule that disclosure of a species provides sufficient written description support for a later filed claim directed to the genus. For example, in the recent case of In re Curtis, 354 F.3d 1347 (Fed. Cir. 2004),

this court affirmed the Board's rejection of claims directed to dental floss for failure to satisfy the written description requirement. The relevant parent application only disclosed the use of microcrystalline wax as adhered to polytetrafluoroethylene floss. However, the claims in the continuation-in-part application were more broadly drawn to the genus of friction enhancing coatings applied to polytetrafluoroethylene floss. This court explained that the evidence relied on by the Board in determining that the later claims were not entitled to priority to the parent application indicated that at the time the parent application was filed no one knew of any material other than microcrystalline wax that would adhere to the polytetrafluoroethylene floss. Id. at 1352-53. This court then distinguished In re Smythe by explaining that the Board properly found that this particular field was unpredictable. "Unlike the circumstances In re Smythe presented, the instant facts present a case in which there is 'unpredictability in performance of certain species or subcombinations other than those specifically enumerated.'" Id. at 1355 (quoting In re Smythe, 480 F.2d at 1383). Thus, unpredictability in the particular field may warrant closer scrutiny of whether disclosure of a species is sufficient to describe a genus.

The distinction in these cases is based upon what would be reasonably conveyed to a person skilled in the art at the time of the original disclosure. If the difference between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members, i.e., if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.

Another exception is presented in Tronzo v. Biomet, Inc., 156 F.3d 1154 (Fed. Cir. 1998). In Tronzo, this court held that substantial evidence did not support the jury's verdict that claims to a hip prosthesis of generic shape were supported by a parent disclosing only a trapezoidal shape. We said, "Instead of suggesting that the '589 patent [the parent] encompasses additional shapes, the specification specifically distinguishes the prior art as inferior and touts the advantages of the conical shape of the '589 cup. Such statements make clear that the '589 patent discloses only conical shaped cups and nothing broader." Id. at 1159 (citation omitted).

In analyzing the written description question in this case, the Board made much of how the "written description must actually describe the later-claimed invention, not just enable it or provide information to render it obvious." Original Decision, slip op. at 25. However, the Board never truly discussed the understandings of persons skilled in the art and whether Bilstad's written description would reasonably convey to a person skilled in the art that Bilstad had possession of the claimed subject matter at the time of filing. Specifically, the Board made no findings on the unpredictability in the art or on whether Bilstad's disclosure expressly disclaimed manipulation in a larger number of directions than the "small number" that the Board found his disclosure taught. The Board relied heavily on Tronzo. Original Decision, slip op. at 24-25. However, the Board failed to recognize how Tronzo fits within the spectrum of cases involving written description support for a genus when only one or more species are disclosed. In the mechanical world—a fairly predictable field—it is wholly conceivable that manipulation in a small number of directions may convey to one skilled in the art that Bilstad indeed described manipulation in a "plurality" of directions. See In re Curtis, 354 F.3d at 1354-

55 (holding that an application would not have put persons skilled in the art on notice of the broad scope claimed by the applicant, where there is “unpredictability in performance of certain species or subcombinations other than those specifically enumerated” (quoting In re Smythe, 480 F.2d at 1383)). But the record contains no analysis of what one skilled in the art would have understood from the Bilstad disclosure or the degree of predictability of technical variations in this field of art. The Board noted that Bilstad’s written description disclosed manipulating objects in only a small number of directions and concluded that this was insufficient to support the manipulation of objects in a range bounded by two and infinity. Original Decision, slip op. at 24. Under the circumstances of this case, however, the Board erred in failing to consider the knowledge of one skilled in the art and the level of predictability in the field.

Even though the appeal is properly before us, a resolution of the question of whether Bilstad’s disclosure of manipulation in a small number of directions would reasonably convey to a person skilled in the relevant art that Bilstad had possession of manipulation in a plurality of directions as of his filing date requires fact findings this court is not permitted to make. Accordingly, we vacate the Board’s decision with respect to the written description requirement and remand for reconsideration under the proper test for support of the count.

C. Denial of Bilstad’s § 1.635 Motion

Bilstad also argues that the Board erred in rejecting Bilstad’s motion under § 1.635 seeking permission to belatedly file its motion under 37 C.F.R. § 1.633(i). In particular, Bilstad argues that the Board “assured Bilstad that it would have every opportunity to file those motions” on denying Bilstad’s request for an extension of time,

but then prejudiced Bilstad by refusing later to entertain Bilstad's belated motion under § 1.633(i). Wakalopulos argues that the Board did not abuse its discretion in denying Bilstad's motion because Bilstad's motion under § 1.635 seeking leave to file the § 1.633(i) motion out of time did not comply with the Board's standing order requiring a conference call with the Administrative Patent Judge prior to the filing of any miscellaneous motion and because the Board provided Bilstad no assurances that it would be permitted to file a Rule 633(i) motion out of time. We agree that Bilstad failed to comply with the Board's standing order requiring a conference call with the Administrative Patent Judge prior to filing the miscellaneous motion under Rule 635. Bilstad argues that the call had already been made and that the Administrative Patent Judge had granted permission to file the motion, citing the portion of the Administrative Patent Judge's order denying his original motion without prejudice. The Administrative Patent Judge, however, did not grant Bilstad permission to file the late motion. He simply denied Bilstad's original motion without prejudice. Thus, Bilstad was starting over when filing the Rule 635 motion, and Bilstad had to comply with the Board's standing order regarding motions under Rule 635. Because the Board did not abuse its discretion in rejecting Bilstad's Rule 635 motion seeking permission to file a belated Rule 633(i) motion, we affirm that portion of the Board's Reconsideration Decision.

III. CONCLUSION

Because the Board did not abuse its discretion in denying Bilstad's motion to file a Rule 633(i) motion out of time, we affirm that portion of the Board's decision. We also affirm the Board's construction of "plurality." However, because the Board failed to apply the appropriate standard in its analysis of whether Bilstad's application included

sufficient written description to support the count under 35 U.S.C. § 112, ¶ 1, we vacate the Board's grant of Wakalopulos's motion for judgment and remand to the Board for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

IV. COSTS

No costs.